STATUTORY INSTRUMENTS

2016 No. 1107

The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016

PART 2

Obligations of economic operators

Chapter 1

Manufacturers

Design and manufacture in accordance with essential health and safety requirements

5. Before placing a product on the market or using a product for their own purposes, a manufacturer must ensure that it has been designed and manufactured in accordance with the essential health and safety requirements.

Commencement Information

I1 Reg. 5 in force at 8.12.2016, see **reg. 1(1)**

Technical documentation and conformity assessment

6. Before placing a product on the market or using it for their own purposes, a manufacturer must—

(a) carry out the relevant conformity assessment procedure or have a relevant conformity assessment procedure carried out; and

[[F1](b) draw up the technical documentation referred to—

(i) for a product in respect of which the conformity assessment procedure in regulation 39(1)(a) is being carried out, in paragraph 3(c) of Part 1 of Schedule 3A to these Regulations;

(ii) for a product in respect of which the conformity assessment procedure in regulation 39(1)(b) is being carried out, in paragraph 3(c) of Part 1 of Schedule 3A to these Regulations;

(iii) for a product in respect of which the conformity assessment procedure in regulation 39(1)(c) is being carried out, in paragraph 2 of Part 6 of Schedule 3A to these Regulations;

(iv) for a product in respect of which the conformity assessment procedure in regulation 39(1)(d) is being carried out, in paragraph 2 of Part 7 of Schedule 3A to these Regulations.**]**

F1 Reg. 6(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 5** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I2 Reg. 6 in force at 8.12.2016, see **reg. 1(1)**

[F2Declaration] of conformity and [F3UK] marking

7.—(1) Save for where a product is a component, where the conformity of a product with the essential health and safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the product on the market—

(a) draw up a declaration of conformity in accordance with regulation 40 (F4... declaration of conformity), and

(b) affix the **[**F5UK**]** Marking in accordance with regulation 41 (**[**F5UK**]** Marking).

(2) The manufacturer must keep the F6... declaration of conformity up-to-date.

(3) Where the conformity of a component with the essential health and safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the component on the market, draw up a written attestation of conformity in accordance with regulation 39(3) (conformity assessment procedures).

(4) Subject to paragraph (5), before placing a product on the market, the manufacturer must ensure that each product is accompanied by a copy of the F7... declaration of conformity or attestation of conformity as appropriate.

(5) Where a large number of products are delivered to a single user, the batch or consignment may be accompanied by a single copy of the F8... declaration or attestation of conformity as appropriate.

[F9(6) Where a product is subject to more than one enactment requiring the drawing up of a declaration of conformity, the manufacturer must draw up a single declaration of conformity which identifies each enactment by its title.**]**

F2 Word in reg. 7 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(a)(i)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F3 Word in reg. 7 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(a)(ii)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F4 Word in reg. 7(1)(a) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F5 Word in reg. 7(1)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F6 Word in reg. 7(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F7 Word in reg. 7(4) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F8 Word in reg. 7(5) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(d)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F9 Reg. 7(6) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 6(e)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I3 Reg. 7 in force at 8.12.2016, see **reg. 1(1)**

Retention of technical documentation and [F10]... declaration of conformity

8. A manufacturer must keep the technical documentation and the [F11]... declaration of conformity (or where applicable, the attestation of conformity) drawn up in respect of a product for a period of 10 years beginning on the day on which the product is placed on the market.

F10 Word in reg. 8 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 7** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F11 Word in reg. 8 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 7** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I4 Reg. 8 in force at 8.12.2016, see **reg. 1(1)**

Compliance procedures for series production

9.—(1) A manufacturer of a product which is manufactured by series production must ensure that, before placing a product on the market, procedures are in place to ensure that any product so manufactured will be in conformity with Part 2.

(2) In doing so, the manufacturer must take adequate account of—

(a) any change in the product design or characteristics, and

(b) any change in a **[**[F12]designated**]** standard or in another technical specification by reference to which the [F13]... declaration of conformity or attestation of conformity was drawn up.

F12 Word in reg. 9(2)(b) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 8(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F13 Word in reg. 9(2)(b) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 8(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I5 Reg. 9 in force at 8.12.2016, see **reg. 1(1)**

Monitoring

10.—(1) When appropriate, with regard to the risks to the health and safety of end-users presented by a product, a manufacturer must—

(a) carry out sample testing of a product manufactured by the manufacturer made available on the market,

(b) investigate complaints that a product manufactured by the manufacturer is not in conformity with Part 2, and

(c) keep distributors informed of any actions carried out under sub-paragraphs (a) and (b).

(2) A manufacturer must keep a register of—

(a) complaints that a product is not in conformity with Part 2,

(b) products which are found not to be in conformity with Part 2, and

(c) product recalls.

(3) A manufacturer must keep an entry made in the register for a period of at least 10 years beginning on the day on which the obligation to make the entry arose.

Commencement Information
I6 Reg. 10 in force at 8.12.2016, see **reg. 1(1)**

Labelling and packaging of products

11.—(1) Before placing a product on the market, a manufacturer must ensure that it bears a type, batch or serial number or other element allowing its identification.

(2) If the size or nature of the product does not provide sufficient space for the labelling requirements in paragraph (1), the manufacturer must ensure that the information is provided on the packaging or in a document accompanying the product.

Commencement Information
I7 Reg. 11 in force at 8.12.2016, see **reg. 1(1)**

Labelling and packaging of products, other than components

12. Save for where a product is a component, before placing a product on the market a manufacturer must ensure that it—

(a) bears the specific marking of explosion protection as referred to at paragraph 5(1)(f) of Schedule 1, and

(b) where applicable, bears the other markings and information referred to at paragraph 5 of Schedule 1.

Commencement Information
I8 Reg. 12 in force at 8.12.2016, see **reg. 1(1)**

Information identifying manufacturer

13.—(1) Before placing a product on the market, a manufacturer must indicate on the product—

(a) the name, registered trade name or registered trade mark of the manufacturer, and

(b) a postal address at which the manufacturer can be contacted.

(2) Where it is not possible to indicate the information specified in paragraph (1) on the product, the manufacturer must indicate that information—

(a) on the product packaging, or

(b) in a document accompanying the product.

[F14(3) The information specified in paragraph (1) must be in a language which can be easily understood by end users and the market surveillance authority.**]**

F14 Reg. 13(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 9** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I9 Reg. 13 in force at 8.12.2016, see **reg. 1(1)**

[F15Provision of instructions and safety information

14. When placing a product on the market, a manufacturer must ensure that a product is accompanied by instructions and safety information that are clear, legible and in easily understandable English.**]**

F15 Reg. 14 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 10** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Duty to take action in respect of a product placed on the market which is considered not to be in conformity

15.—(1) A manufacturer who considers, or has reason to believe, that a product which the manufacturer has placed on the market is not in conformity with Part 2, must immediately take the corrective measures necessary to—

(a) bring the product into conformity,

(b) withdraw the product, or

(c) recall the product.

(2) Where the product presents a risk, the manufacturer must immediately inform the market surveillance authorityF16... of the risk, giving details of—

(a) the respect in which the product is considered not to be in conformity with Part 2, and

(b) any corrective measures taken.

F16 Words in reg. 15(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 11** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I10 Reg. 15 in force at 8.12.2016, see **reg. 1(1)**

Provision of information and cooperation

16.—(1) A manufacturer must, further to a reasoned request from the market surveillance authority, and within such period as the market surveillance authority may specify, provide the authority with the information and documentation necessary to demonstrate that the product is in conformity with Part 2—

(a) in paper or electronic form, and

(b) in a language which can be easily understood by the market surveillance authority.

(2) A manufacturer must, at the request of the market surveillance authority, cooperate with the authority on any action taken to—

(a) evaluate a product in accordance with regulation 55 (evaluation of a product presenting a risk);

(b) eliminate the risks posed by a product which the manufacturer has placed on the market.

Commencement Information

I11 Reg. 16 in force at 8.12.2016, see **reg. 1(1)**

Authorised representatives

17.—(1) A manufacturer may, by written mandate, appoint a person established in the **[**F17United Kingdom**]** as their authorised representative to perform specified tasks on the manufacturer's behalf.

(2) A manufacturer who has appointed an authorised representative to perform, on the manufacturer's behalf, a task under these Regulations remains responsible for the proper performance of that task.

(3) The obligations laid down in regulation 5 (design and manufacture in accordance with essential health and safety requirements) and regulation 6(b) (technical documentation and conformity assessment) must not form part of an authorised representative's mandate.

(4) The mandate must allow the authorised representative to do at least the following in relation to a product covered by the mandate—

(a) perform the manufacturer's obligations under regulation 8 (retention of technical documentation and F18... declaration of conformity), and

(b) perform the manufacturer's obligations under regulation 16 (provision of information and cooperation).

(5) An authorised representative must comply with all duties imposed on the manufacturer in relation to each obligation under these Regulations that the authorised representative is appointed by the mandate to perform and, accordingly as far as those duties are concerned, as well as the penalties for failure to comply with those duties, references in these Regulations (except in this regulation) to the manufacturer are to be taken as including a reference to the authorised representative.

F17 Words in reg. 17(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 12(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F18 Word in reg. 17(4)(a) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 12(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I12 Reg. 17 in force at 8.12.2016, see **reg. 1(1)**

Chapter 2

Importers

Prohibition on placing on the market products which are not in conformity

18. An importer must not place a product on the market unless it is in conformity with the essential health and safety requirements.

Commencement Information
I13 Reg. 18 in force at 8.12.2016, see **reg. 1(1)**

Requirements which must be satisfied before an importer places a product on the market

19.—(1) Before placing a product on the market, an importer must ensure that—

(a) a relevant conformity assessment procedure has been carried out by the manufacturer,

(b) the manufacturer has drawn up the technical documentation,

(c) the product—

(i) bears the **[**F19UK**]** marking where applicable,

(ii) is accompanied by the F20... declaration of conformity or the attestation of conformity as appropriate, and

(iii) is accompanied by the required documents, and

(d) the manufacturer has complied with the requirements set out in regulation 11 (labelling and packaging of products), regulation 12 (labelling and packaging of products, other than components) and regulation 13 (information identifying manufacturer).

(2) In paragraph (1)(c)(iii), "required documents" means any documents that are required to be provided with a product pursuant to—

(a) regulation 11(2) (labelling and packaging of products);

(b) regulation 13(2)(b) (information identifying manufacturer);

(c) regulation **[**F21**]**14 (provision of instructions and safety information)**]**.

F19 Word in reg. 19(1)(c)(i) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 13(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
F20 Word in reg. 19(1)(c)(ii) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 13(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
F21 Words in reg. 19(2)(c) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 13(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information
I14 Reg. 19 in force at 8.12.2016, see **reg. 1(1)**

Prohibition on placing on the market products considered not to be in conformity with the essential health and safety requirements

20.—(1) Where an importer considers, or has reason to believe, that a product is not in conformity with the essential health and safety requirements, the importer must not place the product on the market.

(2) Where the product presents a risk, the importer must inform the manufacturer and the market surveillance authority of that risk.

Commencement Information

I15 Reg. 20 in force at 8.12.2016, see **reg. 1(1)**

Information identifying importer

21.—(1) Before placing a product on the market, an importer must indicate on the product—

(a) the name, registered trade name or registered trade mark of the importer, and

(b) a postal address at which the importer can be contacted.

(2) The information specified in paragraph (1) must be in a language which can be easily understood by end-users and **[**[F22]the market surveillance authority**]**.

[[F23](3) Paragraph (1) does not apply where—

(a) either—

(i) it is not possible to set out the information referred to in paragraph (1) on the product, or

(ii) the importer has imported the product from an EEA state or Switzerland and places it on the market within the period of **[**[F24]seven years**]** beginning with IP completion day, and

(b) before placing the product on the market, the importer sets out the information referred to in paragraph (1)—

(i) on the packaging; or

(ii) in a document accompanying the product.**]**

F22 Words in reg. 21(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 14(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F23 Reg. 21(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 14(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2019/1246, regs. 1(3), **5** and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 2(1)(i)** and S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(n)(iii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F24 Words in reg. 21(3)(a)(ii) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 4, **Sch. 3**

Modifications etc. (not altering text)

C1 Reg. 21 modified (temp.) (10.9.2019) by S.I. 2019/392, reg. 6 (as inserted by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(2)(4), **2(3)** (with reg. 18))

Commencement Information
I16 Reg. 21 in force at 8.12.2016, see **reg. 1(1)**

[F25Provision of Instructions and safety information

22. When placing a product on the market, an importer must ensure that the product is accompanied by instructions and safety information that are clear, legible and in easily understandable English.**]**

F25 Reg. 22 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 15** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Storage and transport

23. Each importer must ensure that, whilst a product is under that importer's responsibility, its storage or transport conditions do not jeopardise its conformity with the essential health and safety requirements.

Commencement Information
I17 Reg. 23 in force at 8.12.2016, see **reg. 1(1)**

Monitoring

24.—(1) When deemed appropriate, with regard to the risks to the health and safety of end-users presented by a product, an importer must—

(a) carry out sample testing of a product made available by the importer on the market,

(b) investigate complaints that a product placed on the market by the importer is not in conformity with Part 2, and

(c) keep distributors informed of actions carried out under sub-paragraphs (a) and (b).

(2) An importer must keep a register of—

(a) complaints that a product is not in conformity with Part 2,

(b) products which are found not to be in conformity with Part 2, and

(c) product recalls.

(3) An importer must keep an entry made in the register for a period of at least 10 years beginning on the day on which the obligation to make the entry arose.

Commencement Information
I18 Reg. 24 in force at 8.12.2016, see **reg. 1(1)**

Duty to take action in respect of a product placed on the market which is considered not to be in conformity

25.—(1) An importer who considers, or has reason to believe, that a product which the importer has placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

(a) bring the product into conformity,

(b) withdraw the product, or

(c) recall the product.

(2) Where the product presents a risk, the importer must immediately inform the market surveillance authority[F26]... of the risk, giving details of—

(a) the respect in which the product is considered not to be in conformity with Part 2, and

(b) any corrective measures taken.

F26 Words in reg. 25(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 16** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I19 Reg. 25 in force at 8.12.2016, see **reg. 1(1)**

Provision of information and cooperation

26.—(1) An importer must, further to a reasoned request from the market surveillance authority and within such period as the market surveillance authority may specify, provide the authority with the information and documentation necessary to demonstrate that the product is in conformity with Part 2—

(a) in paper or electronic form, and

(b) in a language which can be easily understood by the market surveillance authority.

(2) An importer must, at the request of the market surveillance authority, cooperate with the authority on any action taken to—

(a) evaluate a product in accordance with regulation 55 (evaluation of a product presenting a risk);

(b) eliminate the risks posed by the product which the importer has placed on the market.

Commencement Information

I20 Reg. 26 in force at 8.12.2016, see **reg. 1(1)**

Retention of technical documentation and [F27]... declaration of conformity

27. An importer must, for a period of ten years beginning on the day on which the product was placed on the market, keep and, upon request, make available to the market surveillance authority—

(a) a copy of the [F28]... declaration of conformity or, where applicable, the attestation of conformity, and

(b) the technical documentation.

F27 Word in reg. 27 heading omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 17** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F28 Word in reg. 27 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 17** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I21 Reg. 27 in force at 8.12.2016, see **reg. 1(1)**

Chapter 3

Distributors

Duty to act with due care

28. When making a product available on the market, a distributor must act with due care to ensure that it is in conformity with Part 2.

Commencement Information

I22 Reg. 28 in force at 8.12.2016, see **reg. 1(1)**

Requirements which must be satisfied before a distributor makes a product available on the market

29.—(1) Before making a product available on the market, the distributor must verify that—

(a) the product—

(i) bears a **[**[F29]UK**]** marking where applicable;

(ii) is accompanied by the [F30]... declaration of conformity or the attestation of conformity;

(iii) is accompanied by the required documents;

[[F31](iv) is accompanied by instructions and safety information that are clear, legible and in easily understandable English;**]**

(b) the manufacturer has complied with the requirements set out in regulation 11 (labelling and packaging of products), regulation 12 (labelling and packaging of products, other than components) and regulation 13 (information identifying manufacturer);

(c) the importer has complied with the requirements set out in regulation 21 (information identifying importer).

(2) In paragraph (1)(a)(iii), "required documents" means the documents that the manufacturer or importer is required to provide with the product pursuant to—

(a) regulation 11(2) (labelling and packaging of products);

(b) regulation 13(2)(b) (information identifying manufacturer);

(c) regulation 21(3)(b) (information identifying importer).

F29 Word in reg. 29(1)(a)(i) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 18(a)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F30 Word in reg. 29(1)(a)(ii) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 18(b)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F31 Reg. 29(1)(a)(iv) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 18(c)** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I23 Reg. 29 in force at 8.12.2016, see **reg. 1(1)**

Storage and transport

30. Each distributor must ensure that, whilst a product is under that distributor's responsibility, its storage or transport conditions do not jeopardise its conformity with the essential health and safety requirements.

Commencement Information

I24 Reg. 30 in force at 8.12.2016, see **reg. 1(1)**

Prohibition on making available on the market where product not considered to be in conformity with safety objectives

31.—(1) Where a distributor considers, or has reason to believe, that a product is not in conformity with the essential health and safety requirements, the distributor must not make the product available on the market.

(2) Where the product presents a risk, the distributor must inform the following persons of the risk—

(a) the manufacturer or the importer, and

(b) the market surveillance authority.

Commencement Information

I25 Reg. 31 in force at 8.12.2016, see **reg. 1(1)**

Duty to take action in respect of products made available on the market which are not in conformity

32.—(1) A distributor who considers, or has reason to believe, that a product which the distributor has made available on the market is not in conformity with Part 2 must make sure that the necessary corrective measures are taken to—

(a) bring that product into conformity,

(b) withdraw the product, or

(c) recall the product.

(2) Where the product presents a risk, the distributor must immediately inform the market surveillance authority[F32]... of that risk, giving details of—

(a) the respect in which the product is considered not to be in conformity with Part 2, and

(b) any corrective measures taken.

F32 Words in reg. 32(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 19** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I26 Reg. 32 in force at 8.12.2016, see **reg. 1(1)**

Provision of information and cooperation

33.—(1) A distributor must, further to a reasoned request from the market surveillance authority and within such period as the authority may specify, provide the authority with the information and documentation, in paper or electronic form, necessary to demonstrate that the product is in conformity with Part 2.

(2) A distributor must, at the request of the market surveillance authority, cooperate with the authority on any action taken to—

(a) evaluate a product in accordance with regulation 55 (evaluation of a product presenting a risk);

(b) eliminate the risks posed by a product which the distributor has made available on the market.

Commencement Information

I27 Reg. 33 in force at 8.12.2016, see **reg. 1(1)**

Chapter 4

Importers and distributors

Cases in which obligations of manufacturers apply to importers and distributors

34. An economic operator ("A") who would, but for this regulation, be considered an importer or distributor, is to be considered a manufacturer for the purposes of these Regulations and is subject to the obligations of the manufacturer under this Part, where A—

(a) places a product on the market under A's own name or trademark; or

(b) modifies a product already placed on the market in such a way that it may affect whether the product is in conformity with Part 2.

Commencement Information

I28 Reg. 34 in force at 8.12.2016, see **reg. 1(1)**

Chapter 5

All economic operators

Identification of economic operators

35.—(1) An economic operator ("E") who receives a request from the market surveillance authority before the end of the relevant period, must, within such period as the authority may specify, identify to the authority—

(a) any economic operator who has supplied E with a product, and

(b) any economic operator to whom E has supplied a product.

(2) The relevant period is—

(a) for information under paragraph (1)(a), a period of 10 years beginning on the day on which E was supplied with the product;

(b) for information under paragraph (1)(b), a period of 10 years beginning on the day on which E supplied the product.

Commencement Information

I29 Reg. 35 in force at 8.12.2016, see **reg. 1(1)**

Prohibition on improper use of [F33UK] marking

36.—(1) An economic operator must not affix the **[**F34UK**]** marking to a product unless—

(a) that economic operator is the manufacturer, and

(b) the conformity of the product with the essential health and safety requirements has been demonstrated by a relevant conformity assessment procedure.

(2) An economic operator must not affix to a product a marking (other than the **[**F34UK**]** marking) which purports to attest that the product is in conformity with the essential health and safety requirements.

(3) An economic operator must not affix to a product a marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the **[**F34UK**]** marking.

(4) An economic operator must not affix to a product any other marking if the visibility, legibility and meaning of the **[**F34UK**]** marking would be impaired as a result.

F33 Word in reg. 36 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 20** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F34 Word in reg. 36 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 20** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I30 Reg. 36 in force at 8.12.2016, see **reg. 1(1)**

[F35Obligations which are met by complying with obligations in the ATEX Directive

36A.—(1) In this regulation—

(a) any reference to an Article or an Annex is a reference to an Article or an Annex of the ATEX Directive;

(b) "CE marking" has the meaning given to it in Article 2(26); and

(c) "harmonised standard" has the meaning given to in in Article 2(18).

(2) Subject to paragraphs (6) and (7) paragraph (3) applies where, before placing the product on the market, the manufacturer—

(a) ensures that the product has been designed and manufactured in accordance with the essential safety requirements set out in Annex II;

(b) ensures that the relevant conformity assessment procedures that apply to that product in accordance with Article 13(1) and (2) have been carried out;

(c) draws up the technical documentation referred to in Annexes III to IX;

(d) ensures that the records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;

(e) affixes a CE marking and the inscriptions in accordance with Articles 15 and 16(1) to (4);

(f) draws up an EU declaration of conformity, in accordance with Article 14; and

(g) ensures that the declaration of conformity is prepared in or translated into English.

(3) Where this paragraph applies—

(a) the requirements of regulations 5, 6, 7(1), (3) and 7(6) are to be treated as being satisfied;

(b) regulations 2(a), 7(6), 8, 9(2), 17(4), 36 and 59 apply subject to the modifications in paragraph (10);

(c) Part 3 does not apply; and

(d) regulation 57 does not apply.

(4) Subject to paragraphs (6) and (7) paragraph (5) applies where, before placing a product on the market, the importer ensures that—

(a) the relevant conformity assessment procedure referred to in Article 13 has been carried out;

(b) the manufacturer has drawn up the technical documents relevant to the conformity assessment procedure followed; and

(c) the product bears the CE marking and inscriptions referred to in point 1.0.5 of Annex II.

(5) Where this paragraph applies—

(a) the requirements of regulation 19(1)(a) to (c) are to be treated as being satisfied; and

(b) regulations 2(a),18, 23 and 27 apply subject to the modifications in paragraph (10).

(6) This paragraph applies where there is no designated standard or part of a designated standard which corresponds exactly to a harmonised standard or part of a harmonised standard referred to in Article 12.

(7) Where paragraph (6) applies, paragraphs (2)(b) and (4)(a) are to be treated as requiring the manufacturer to carry out—

(a) the conformity assessment procedure set out in Article 13(1)(b); and

(b) the relevant conformity assessment procedure that applies to that product in accordance with Article 13(2).

(8) Paragraph (9) applies where, before making a product available on the market, a distributor ensures that the product bears the CE marking and inscriptions referred to in point 1.0.5 of Annex II.

(9) Where this paragraph applies—

(a) regulation 29(1)(a)(i) is to be treated as being satisfied; and

(b) regulations 2(a), 30 and 31(1) apply subject to the modifications in paragraph (10).

(10) The modifications referred to in subparagraphs (3)(b), (5)(b) and (9)(b) are that—

(a) any reference to “declaration of conformity” is to be read as a reference to the EU declaration of conformity;

(b) any reference to “UK marking” is to be read as reference to the CE marking;

(c) any reference to "essential safety requirements" is to be read as a reference to the essential safety requirements referred to in Annex II;

(d) any reference to "designated standard" is to be read as a reference to a harmonised standard;

(e) any reference to "relevant conformity assessment procedure" is to be read as a reference to the relevant conformity assessment procedures referred to in Article 13;

(f) any reference to "technical documentation" is a reference to the technical documentation referred to in Annexes III to IX.

F35 Regs. 36A-36D inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 21** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**) (as amended by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 17(3)); 2020 c. 1, **Sch. 5 para. 1(1)**

Conformity assessment procedure obligation which is met by complying with the ATEX Directive

36B.—(1) In this regulation any reference to an Article or Annex is a reference to an Article or an Annex of the ATEX Directive;

(2) Paragraph (3) applies where, prior to the manufacture of a product, the manufacturer ensures that the conformity assessment procedure that applies to that product in accordance with Annex III as referred to in Article 13(1)(a) and (b) has been carried out.

(3) Where this paragraph applies—

(a) any requirement to follow the Type-examination set out in Part 1 of Schedule 3A in regulation 39 is to be treated as being satisfied;

(b) any reference to "relevant conformity assessment procedure" in regulations 6(a), 7(1), 19(a), 36(1)(b), 40(c) and 41(3) is to be read as including the conformity assessment procedure set out in Annex III as referred to in Article 13(1)(a) and (b); and

(c) any reference to "technical documentation" in regulations 6(b), 8, 19(b) and 27(b) is to be read as including the technical documentation relating to the design of the product referred to in Annex III.

F35 Regs. 36A-36D inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 21** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**) (as amended by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 17(3)); 2020 c. 1, **Sch. 5 para. 1(1)**

Expiry of regulations 36A and 36B

36C.—(1) Subject to paragraph (2), regulation 36A ceases to have effect at the end of the period of **[**F36four years**]** beginning with IP completion day.

(2) Notwithstanding the expiry of regulation 36A—

(a) any product which was placed on the market pursuant to regulation 36A may continue to be made available on the market on or after the expiry of regulation 36A;

(b) any obligation to which a person was subject under regulation 36A in respect of any product placed on the market pursuant to regulation 36A continues to have effect after the expiry of regulation 36A, in respect of that product.

(3) Subject to paragraph (4), regulation 36B ceases to have effect at the end of the period of **[**[F37]four years**]** beginning with IP completion day.

(4) Where a conformity assessment procedure has been completed pursuant to regulation 36B in relation to a product prior to the expiry of regulation 36B, regulation 36B continues to apply in respect of that pressure equipment or assembly where—

(a) the manufacturer arranges for the EU-Type examination certificate and any annexes to be transferred to an approved body;

(b) the approved body referred to in sub-paragraph (a) accepts responsibility for the EU-Type examination certificate; and

(c) the approved body issues a Type-examination certificate relying, or relying in part, on any examinations or tests undertaken prior to the issue of the EU-Type examination certificate.

(5) In paragraph (4) "EU-Type examination certificate" means a certificate issued after the conformity assessment referred to in regulation 36B(2) has been carried out.

F35 Regs. 36A-36D inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 21** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**) (as amended by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 17(3)); 2020 c. 1, **Sch. 5 para. 1(1)**

F36 Words in reg. 36C(1) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 2, **Sch. 1**

F37 Words in reg. 36C(3) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 2, **Sch. 1**

Qualifying Northern Ireland Goods

36D.—(1) In this regulation—

"the 2017 Regulations" means the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2017;

"CE marking" has the meaning given to it in regulation 2(1) of the 2017 Regulations;

"qualifying Northern Ireland goods" has the meaning given to it in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

"relevant conformity assessment procedure" has the meaning given to it in regulation 2(1) of the 2017 Regulations;

"technical documentation" has the meaning given to it in regulation 2(1) of the 2017 Regulations.

(2) Where paragraph (3) applies, a product is to be treated as being in conformity with Part 2.

(3) This paragraph applies where—

(a) a product—

(i) is in conformity with Part 2, within the meaning of regulation 2(2) of the 2017 Regulations; and

(ii) is qualifying Northern Ireland goods; and

(b) an importer has complied with the obligations set out in paragraph (4).

(4) The obligations referred to in paragraph (3)(b) are that, before placing the product on the market, the importer—

(a) complies with regulation 21;

(b) ensures that—

(i) the relevant conformity assessment procedure has been carried out in relation to the product;

(ii) the manufacturer has drawn up the technical documentation; and

(iii) the product bears the CE marking.**]**

F35 Regs. 36A-36D inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 21** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), **2**) (as amended by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 17(3)); 2020 c. 1, **Sch. 5 para. 1(1)**

Translation of declaration of conformity

[F38 37. . . . . . .

F38 Reg. 37 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 25 para. 22** (with Sch. 25 para. 34) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:
There are currently no known outstanding effects for the The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016, PART 2.